K002822

JAN 31 2001

SECTION 14: SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92.

14.1 SUBMITTER INFORMATION

a. Company Name:	Medical Positioning, Inc.
b. Company Address:	2001 Wyandotte Kansas City, MO 64108
c. Company Phone: Company Facsimile:	(816) 474-1555 (816) 474-7755
d. Contact Person:	John R. Gordon Vice President & CFO
e. Date Summary Prepared:	August 28, 2000

14.2. DEVICE IDENTIFICATION

a. Trade/Proprietary Name:	Vertex System
b. Classification Name:	Electrocardiograph 21 CFR 870.2340

14.3 IDENTIFICATION OF PREDICATE DEVICE

Company	Device	510(k) No.	Date Cleared
Biosensor Corp.	PC-ECG 1200 ECG and Stress Electrocardiograph System	K960449	05/30/96
Quinton	Q4500 Stress Test System	K910017	11/05/91
GE Marquette	CENTRA/CASE 8000 Exercise Testing System	K935589 K991914	08/24/95 10/20/99

14.4 DEVICE DESCRIPTION

The Vertex System is a complete integrated stress echocardiography system. The Vertex System combines the Stress Echo™ Bed / Table with an electrocardiograph. The Stress Echo™ Bed provides an exercise source that delivers programmable, controlled variable resistance, while the ECG provides the patient monitoring and recording. Several models of the Stress Echo Bed/Table are available with features that include height adjustability, Trendelenburg, dual, lateral tilt, and computer controllers.

14.5 SUBSTANTIAL EQUIVALENCE

The Vertex System is substantially equivalent to the PC-ECG 1200 ECG and Stress Electrocardiography System in commercial distribution by Biosensor Corporation. The Vertex System and the predicate device incorporate the same electrocardiograph. The Vertex System is substantially equivalent to the Q4500 Stress Test System in commercial distribution by Quinton Instruments and the CENTRA/CASE 8000 Exercise Test System in commercial distribution by GE Marquette Electronics, Inc.

The fundamental technical characteristics of the Vertex System are similar to those of the predicate devices and are listed on the comparison charts provided in this 510(k) submission. The Vertex System and the predicate devices function by providing the user with an integrated exercise source and electrocardiograph for use during cardiovascular monitoring.

14.6 INTENDED USE

The Vertex System is intended for use in stress echocardiography examination. The Vertex System provides an exercise source that delivers programmable, controlled variable resistance.

The Vertex System incorporates an electrocardiograph that records either normal conditions or patterns of arrhythmia and/or rate abnormalities in patients. In addition, the Vertex System provides "QRS" complex to a cardiac ultrasound device to be used to capture images (heart beats), either digitally or on videotape, such that each image begins at the time systole begins.

14.7 TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the Vertex System are similar to those of the predicate devices. The Vertex System utilizes a supine bicycle for the exercise source. Preprogrammed exercise protocols are run for purposes of electrocardiographic monitoring. The ECG used in the Vertex System is identical to the one present in the Biosensor PC-ECG 1200 Stress Electrocardiography System. ECG reports, trends, averages and ST segments are printed by the Vertex System. The Vertex System is connected using standard patient electrodes and leads that are not included in the system.

14.8 PERFORMANCE DATA

The Vertex System was subjected to performance bench testing. Physical performance studies were conducted to verify that the Vertex System performed as intended. In addition, the Vertex System was tested to conformance with UL and IEC safety standards for electrical medical equipment.

14.9 510(K) CHECKLIST

This notification contains all information required by 21 CFR 807.87. A completed copy of the Premarket Notification 510(k) Reviewer's Checklist is provided in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 31 2001

Ms. Carol Patterson
Medical Positioning, Inc.
c/o Patterson Consulting Group, Inc.
21911 Erie Lane
Lake Forest, CA 92630

Re: K002822
Trade Name: The Vertex System
Regulatory Class: II (two)
Product Code: DPS
Dated: December 15, 2000
Received: December 18, 2000

Dear Ms. Patterson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might

have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800).638-2041 or (301) 443-6597.or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number:

Device Name: Vertex System

Indications for Use: The Vertex System is intended for use in stress echocardiography examination. The Vertex System provides an exercise source that delivers programmable, controlled variable resistance.

The Vertex System incorporates an electrocardiograph that records either normal conditions or patterns of arrhythmia and/or rate abnormalities in patients. In addition, the stress echo workstation provides "QRS" complex to a cardiac ultrasound device to be used to capture images (heart beats), either digitally or on videotape, such that each image begins at the time systole begins.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K002822

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)